

REMARKSA. REQUEST FOR RECONSIDERATION

Applicants have carefully considered the matters raised by the Examiner in the outstanding Office Action but remain of the opinion that patentable subject matter is present. Applicants respectfully request reconsideration of the Examiner's position based on the amendments to the claims and the following remarks.

B. STATUS OF THE CLAIMS

In the Office Action, claims 7-10 had been examined. This Response amends claim 7 to add the limitations of claims 8 and 9 and cancels claims 8 and 9. Thus, claims 7 and 10 are the only claims pending in this case.

Claim 7 has also been amended to address the 112 issue which is discussed in more detail below.

C. REJECTIONS UNDER 35 U.S.C. § 112

Claim 7 had been rejected as being indefinite because the phrase "modified cyclodextrin" was deemed ambiguous. Claim 7 has been amended to insert the language of claim 8 and specify that the modified cyclodextrin is hydroxypropylated beta-cyclodextrin.

Claim 7 had also been rejected as indefinite because of the passage "of said product less than or equal". Claim 7 has been amended to clarify that "...said product..." "has a particle size of". Thus, the limitation to "200 microns" and "20 microns" has been amended to clarify that both of these limitations are directed to the particle size of the products. Support for these amendments can be found on page 9, lines 5 and 8 of the application. Respectfully, no new matter has been entered by way of these amendments.

D. REJECTIONS UNDER 35 U.S.C. § 103

Claim 7-10 had been rejected as unpatentable over a combination of Shah and Walsh or Giacobello or Fuertes.

Shah had been cited to teach that drum drying of sulfoalkyl ether cyclodextrin (a modified cyclodextrin) is conventional.

Walsh had been cited to teach typical characteristics of drum driers, namely, steam heating at 10-150 psi, varying the gap between the drums to vary the gap between the drums to vary the particles size of the product, and drying the product to a moisture content of 5-12%.

Giacobello had been cited to teach that drum drying improves the agglomeration of a product.

Fuertes had been cited to teach that hydroxypropylated beta-cyclodextrin is known to dissolve in water in less than 5 minutes.

It is submitted that the way the examiner has put together the reference is based on hindsight because a fair reading of the reference teaches away from the present invention.

Applicants invention solved a problem that existed in the art with, albeit, a simple method. The art, although recognizing the problem, had a different solution to the problem. In fact, because the art choose a different solution, it is submitted that the art teaches away from the solution that applicants' discovered. Respectfully, the art does not teach or suggest the solution arrived at by applicants, and in fact teaches away from the solution arrived at by the present invention. Thus, it is respectfully submitted that the examiners combination of the references is hindsight.

The problem in the art was dusting and the slow dissolution of dried, modified cyclodextrin, see page 2, second full paragraph in the application. This problem was also recognized in the art. In column 2, at lines 27-30, Fuertes recognizes the poor dissolution of modified cyclodextrin. At lines 33-39 of column 2, Fuertes

recognizes the dusting problem. All of these problems are attributable to either spray drying or freeze-drying the modified cyclodextrin.

In order to solve these problems, Fuertes teaches a special spray tower where the aqueous slurry of modified cyclodextrin is sprayed onto a moving bed of pulverized modified cyclodextrin, see column 5, lines 20-34. Also, see the paragraph bridging pages 2 and 3 of the application for a discussion of Fuertes. Thus, Fuertes recognized the dusting and poor dissolution problem and solves the problem by a different method, spraying a slurry of hydroxypropylated beta-cyclodextrin onto a moving bed of modified cyclodextrin.

Shah does not recognize the problem of the present invention. Shah is concerned with making a sulfoalkylated ether cyclodextrin not avoiding a dusting problem or a poor dissolution problem of a dried, modified cyclodextrin. Shah suggests freeze drying, spray drying and vacuum drum drying, see column 3, line 26. Thus, Shah equates all three methods. In Shah's examples he dries by a special Buchii apparatus, column 7, line 54, freeze drying, column 8 line 35, or rotary evaporation, column 8, line 64. Thus, Shah does not point one of skill in the art to drum drying, but rather points away from a drum drier because each of

the examples teaches a different drying method, none of which are drum drying.

Thus, if one of skill on the art had a dusting problem and poor dissolution problem, with modified cyclodextrin, the combination of Shah and Fuertes would lead one to the special procedure outlined in Fuertes because Fuertes teaches a special method for solving the problem.

Furthermore, because Fuertes teaches that the solution to applicants' problem is a special spray drying method, one of skill in the art is lead away from any other method. Thus, Fuertes teaches away from the method of the present invention. This is a secondary consideration of obviousness which must be considered and which weights against the obviousness of the present invention.

Giacobello and Walsh are directed to drying very different materials than that in the present invention. Probably the closest, Giacobello, is directed to drying a water absorbent, water insoluble composition. In contrast, the hydroxypropylated beta-cyclodextrin is neither water absorbent nor water insoluble. Rather, hydroxypropylated beta-cyclodextrin is highly water soluble. Thus, Giacobello is directed to a product that has characteristics that are opposite from the product produced by the claimed method.

Furthermore, Giacobello is not directed to the same problem as the present invention. Giacobello is directed to "wet-out" of water absorbing material, see column 2 lines 31-33. Thus, to solve the dusting problem and the dissolution problem of the present invention, one of skill in the art would not turn to Giacobello because it is directed to a composition that is directly opposite the present invention and because Giacobello does not address the problems addressed and solved in the present invention.

Walsh is directed to bean pastes and teaches that its bean paste can be dried by belt driers, spray driers, fluid bed driers, drum driers and troy driers, see column 6, lines 3-4. In Walsh's single example, he teaches four drum driers in sequence, see column 7, line 38. Walsh, like Shah and Giacobello, is not directed to the problem which is solved by the present invention. Thus, Walsh is combination with Shah does not lead one of skill in the art to the present invention because Walsh is not directed to the problems solved in the present invention.

Furthermore, because the product produced in Walsh, bean paste, is unrelated to hydroxypropylated beta-cyclodextrin, it is submitted that one of skill in the art

would not even look to Walsh for help in solving the problem of poor dissolution and dusting.

Finally, consideration should be given to the unique properties provided to the product of the present invention by the method of the present invention. These unique properties are outlined in the Sikorski Declaration submitted on September 13, 2003. As brought out by Mr. Sikorski in paragraph 15 of his Declaration, he finds the difference in the properties between the spray dried product and the drum dried product to be surprising and unexpected for a cyclodextrin product. Some weight must be given to the fact that an unexpected product is produced by the method.

In conclusion, neither Shah, Walsh nor Giacobello are directed to the dusting problem and the dissolution problem of the present invention. Only Fuertes recognizes the dusting and dissolution problem. It is submitted that the references, if properly combined, teach that the special procedure in Fuertes should be followed, not the method of the present invention.

E. CONCLUSION

In view of the foregoing, it is believed that the present Application is now ready for allowance, and such action is respectfully requested. Should any fees or extensions of time be necessary in order to maintain this Application in pending condition, appropriate requests are hereby made and authorization is given to debit account #02-2275.

Respectfully submitted,

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